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510(K) Summary K09 .

SEP - 3 2009

Submitter

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Summary prepared: July 29, 2009

Device Name:

Common/Usual Name: Auditory Evoked Potential System
Trade/Proprietary name: ICS CHARTR EP 200
Classification name: Stimulator, Auditory, Evoked Response

Predicate devices

The GN Otometrics ICS CHARTR EP 200 is similar to these relevant Chartr products:
K031986, ICS Medical Chartr EP with ASSR and Chartr OAE System
Product Code: EWO
Regulation Number: 882.1050

K083399, ICS CHARTR EP 200
Product Code: GWJ
Regulation Number: 882.1900 (without ASSR and Chartr OAE System)

The modified ICS CHARTR EP 200 has the same external hardware platform with USB connection to PC as K083399 and it adds ASSR (from K031986) and minor software enhancements and user interface enhancements.

Description

The ICS CHARTR EP 200 is a PC-based system, which consists of software modules for installation on a PC, an isolation transformer, a hardware platform, pre-amp, a mains adapter, stimulation devices and recording devices.
The stimulation and recording devices are connected to the pre-amp, which is connected to the hardware platform, which is connected to the PC via USB cable - no hardware installation inside the PC is required. This submission is for a modification to K083399. The same hardware is used but the software has the additional ASSR (Auditory Steady State Response) feature as implemented on the system described in K031986.

Intended Use

The ICS Chartr EP 200 is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.

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Technological Characteristics

Device Specifications	ICS Medical Chartr EP with ASSR and Chartr OAE K031986 -	ICS Chartr EP 200 K083399	ICS Chartr EP 200 (This submission)
Indication for Use EP	Indication for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway	Indication for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway	Indication for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway
Indication for use OAE	Indication for the determination of cochlear function in infants, children, and adults which provides information about hearing without subjective response from the individual being tested.	Does not have OAE	Does not have OAE
ASSR Protocol (Auditory Steady State Response)	Included	Does not have ASSR	ASSR added.
Software based electrode switching	Not available	Not available	Implemented.
Hardware implementation	PC-based system with built-in hardware and peripherals	PC-based system with external hardware platform and peripherals (USB interface)	PC-based system with external hardware platform and peripherals (USB interface) Identical to K083399
Software	Windows 98	Windows XP	Windows XP
Power source	Mains	Mains	Mains

Safety (Unchanged)

The ICS Chartr EP 200 is designed to provide safety to the patient as well as the user and complies with:

- EN 60601-1:1990, UL 60601-1;2003, CAN/CSA-C22.2 NO 601.1-90:1990 Medical Electrical. Part 1: General requirements for safety.
- EN 60601-1-1:2001 Medical Electrical Equipment. Part 1: General requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems.
- EN 60601-1-2:2001 Medical Electrical equipment. Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests.
- EN 60601-1-4: 2000 Edition 1.1 Consolidated Edition, Medical electrical equipment Part 1-4: General requirements for Safety —collateral Standard: Programmable Electrical Medical Systems.
- EN 60601-2-26: 2002 Medical electrical equipment — Part 2-26: Particular requirements for the Safety of electroencephalographs.
- EN 60601-2-40:1998 Medical electrical equipment — Part 2-40: Particular requirements for the safety of electromyography and evoked response equipment.

Effectiveness (Unchanged)

The ICS CHARTR EP 200 is an Auditory Evoked Response device for replacement of an existing product of a technology type that is available and accepted in the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP - 3 2009

GN Otometrics
c/o Daniel Kamm, P.E.
Submission Correspondent
Kramm & Associates
333 Milford Rd.
Deerfield, IL 60015

Re: K092373
Trade/Device Name: ICS Chartr EP 200
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: II
Product Code: GWJ
Dated: July 29, 2009
Received: August 5, 2009

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092373

Indications for Use

510(k) Number (if known): K092373

Device Name: ICS Chartr EP 200

Indications For Use:

The ICS Chartr EP 200 System is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(K) Number K092373